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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,056	03/31/2004	Maria Dalko	239466US0	4868
22850 7590 04/18/2007 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER BLAND, LAYLA D	
			ART UNIT	PAPER NUMBER
			1609	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		04/18/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/18/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/813,056

Applicant(s)

DALKO ET AL.

Examiner

Layla Bland

Art Unit

1609

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 8, 12-15 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-11 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

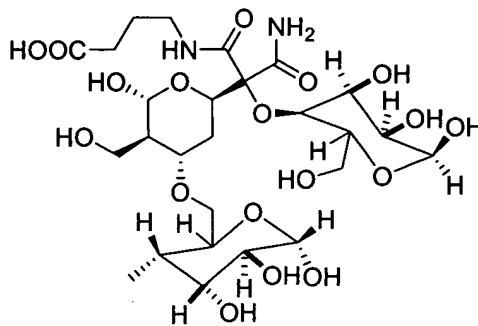
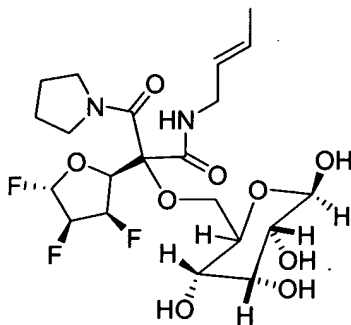
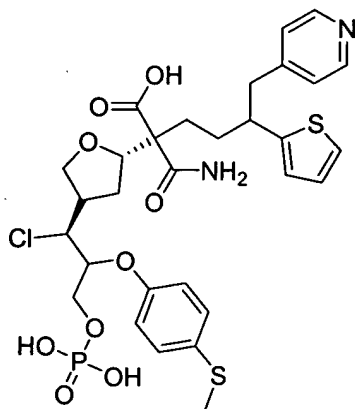
Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 03/31/2004, 01/04/2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This application claims priority to U.S. provisional application 60/471,725 filed May 20, 2003, and to French patent application 0304349 filed April 8, 2003. Applicant's election of, with traverse, of Group I (claims 1-4) and the species of compound G of the specification is acknowledged.

In the response dated February 23, 2007, Mr. Treanor asserts that the present application contains only one independent claim, claim 1. As written, claim 10 is also an independent claim. Mr. Treanor also asserts that the search for each composition and method would occur in the same class/subclass and no burden would be placed on the office to search them all together. A sampling of compounds that could be described by claim 1 reveals structures with no common core (see below) spread across several different subclasses (heterocyclic rings, phosphates, glycosides, etc. all influence classification). Note, also, that the search is not limited to patent files.



Inventions I-VIII and IX-XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the cosmetic processes described in inventions IX-XIII can be practiced with another desquamating agent such as salicylic acid, as mentioned in the instant application. Furthermore, the search for a compound or composition is non-coextensive with the search for the use of that compound, as a reference that renders the compound obvious will not necessarily render the use of that compound obvious. Thus, inventions I-VIII and IX-XIII will not be searched together.

Upon further consideration of the restriction requirement, groups I and VI will be rejoined and the search expanded to include claims 1-7, 9-11 and 16 in part, drawn to a compound of formula (I) wherein the compound is a monosaccharide in pyranose form; $n=1$; R_1 is hydrogen, halogen, or substituted/unsubstituted alkyl, aryl or benzyl not including any heterocycles; R_2 is hydrogen, hydroxyl, hydroxyalkyl, or alkyl; and X and Y are $-OR_3$ or $-NR_3R_4$ where R_3 and R_4 are hydrogen or alkyl.

Claims 8, 12-15 and 17 are withdrawn from consideration as being drawn to a non-elected invention. Claims 1-7, 9-11, and 16 are examined on the merits herein.

Information Disclosure Statement

Only the English abstracts of documents AO-AV of the IDS dated March 31, 2004 were considered. The non-English document AO of the IDS dated January 04, 2006 was not considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites "X and Y form a ring of 6 or 7 carbon atoms with the three carbon atoms separating them." (see page 34, lines 5-9) It is unclear what the total number of atoms in the ring should be, whether the ring is composed only of carbon atoms or if nitrogen and/or oxygen is included in the ring, and whether the "three carbon atoms separating them" are included in the total of 6 to 7 carbon atoms. Dependent claims 2-5 also include this limitation.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 1, the definition of R_2 allows for 0-4 R_2 groups but does not allow for them to be independently defined. They are considered to be identical, which contradicts with many of the examples given in Table 1 of the specification. Claims 2-4 also contain this limitation.

Claim 11 recites the limitation "the compound according to claim 10." Claim 10 is drawn to a derivative, not a compound. There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The three compounds for which the specification contains some data all have specific features in common: $n=1$, X and Y = NHMe, and R_1 (or R_5) = benzyl. A very large number of possible compounds exist which have not been reduced to practice and the specification gives no guidance on structure-function relationships.

See Enzo Biochem, 323 F.3d at 966, 63 USPQ2d at 1615; Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)("[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated."). "A patentee

will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed."

Claims 1-3 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds F, G, and K, (see Table 1, pages 15-18 of the specification) does not reasonably provide enablement for compounds wherein X and Y are other than NHMe, R₅ is other than benzyl, and n=0. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: the invention is a composition comprising compounds of formula (I).

The state of the prior art: Compounds of formula (I) are known in the art but have not been shown to be useful for topical application to the skin.

The relative skill of those in the art: The skill of those in the art is high.

The predictability or unpredictability of the art: Amides (X or Y = N), acids (X or Y = OH) and esters (X or Y = OR) have different chemical properties. Properties to be considered include acidity/basicity, hydrogen bonding, etc. For an example, see Son, et al. (J. Agric. Food Chem. 2002, 50, 468-472) wherein the free radical scavenging and antioxidative activity of caffeic acids, amides, and esters were compared [abstract and Table 1]. The number of hydroxy groups present (R_2 = hydroxy or alkylhydroxy) also has a significant impact on the properties of a compound, including hydrophilicity/hydrophobicity, boiling point, and solubility. Consider, for example, glucose versus tetrahydropyran. Glucose has five hydroxy groups, is very soluble in water and has a melting point of around 146°C while tetrahydropyran has no hydroxy groups, is a liquid at room temperature and has a boiling point of 88°C [CRC Handbook of Chemistry and Physics].

The breadth of the claims: The claims allow for a number of substitutions at R_1 as well as significant functional group substitutions at R_2 , X and Y.

The amount of direction or guidance presented: The specification presents several preferred embodiments of the compound but does not discuss the benefits or detriments of other claimed compounds.

The presence or absence of working examples: One example is given for the preparation of one of the claimed compounds. Batches of isolated stratum corneum

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were incubated in the presence of compounds F, G, and K and the freed corneocytes were counted by microscope. Compounds F, G, and K are structurally similar. In each case, $n=1$, R_1 =benzyl and X and Y = NHMe. No examples are given for the treatment of living skin.

The quantity of experimentation necessary: To practice the invention in keeping with the scope of these claims, a large number of compounds would have to be prepared. Considering the possible functional group substitutions at R_1 , preparation of each of the claimed compounds could require extra synthetic steps besides those presented in the specification. For example, if R_1 represents an alkyl group substituted with $-COOR$ wherein R = ethyl, the ethyl ester could be hydrolyzed in the presence of sodium hydroxide during the final step of the synthesis in Figure 1 to give the acid instead of the target ester. Once prepared, the compounds must be tested. No examples are presented regarding the testing of the claimed compounds on living skin.

Therefore, given the breadth of the claims, the lack of guidance and working examples, the unpredictability in the art, and the state of the art as discussed above, undue experimentation would be required to make and use the claimed invention, and therefore, the invention is not enabled throughout the broad scope of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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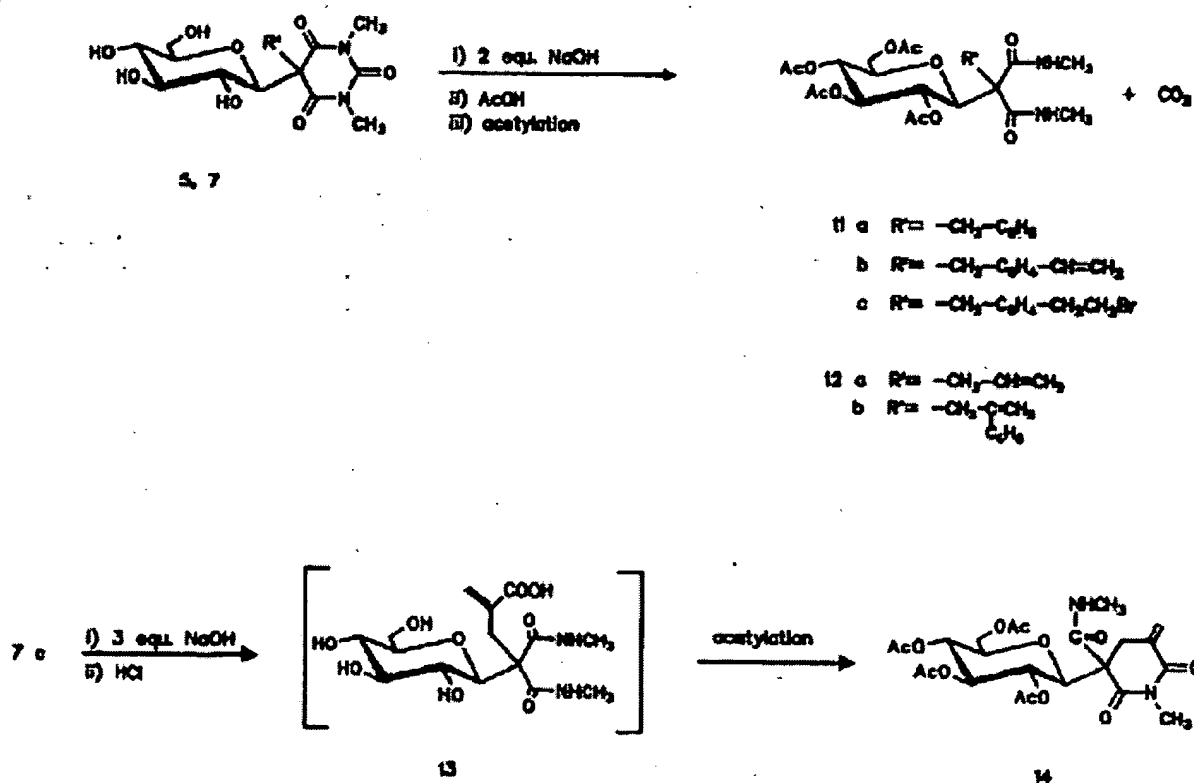
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-7, 9-11 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Wulff, et al. (Carbohydrate Research 257 (1994) 81-95).

Claims 1-7 and 16 are drawn to a composition comprising, in a physiologically acceptable medium, at least one compound of formula (I).

Wulff, et al. teach the following reaction [Scheme 3]:

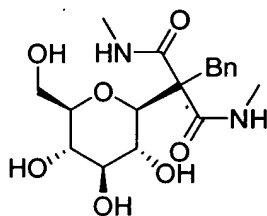


Scheme 3.

The products 11a-c are very similar to the claimed compounds, except that compounds 11a-c are acetylated and the claimed compounds are not. Wulff, et al.

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teach that ^1H NMR spectra of their products were not informative due to the overlapping signals for the glycosyl ring and the allylic or benzylic CH_2 . Therefore, the products were characterized as the tetra-acetates [page 84, lines 4-7]. Experimental details for the production of the above compound 11a include that after hydrolysis of the starting material with sodium hydroxide the compound was acetylated [page 93, *Hydrolysis of barbiturate ring*]. The intermediate 13 clearly shows that the free hydroxy functions of the compound are intact before acetylation. Therefore, the following compound with free hydroxy functions, which meets the limitations of claims 1, 3-7, 9-11, and 16, is present in the reaction before the acetylation step:

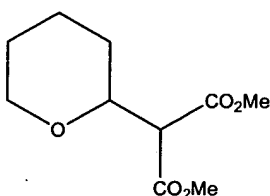


As applied to claims 1, 3, and 4, $n=1$, $R_2 = \text{OH}$ or CH_2OH , $R_1 = \text{benzyl}$, and X and $Y = \text{NR}_3\text{R}_4$, in which R_3 and R_4 are hydrogen and a C_1 alkyl group. As applied to claims 5 and 7, S represents a monosaccharide (glucose) comprising at least one free hydroxyl function and $R_1 = \text{benzyl}$. As applied to claims 6, 9 and 16, S is a monosaccharide comprising at least one free hydroxyl function (glucose) and $R_5 = \text{benzyl}$. According to the experimental details provided by Wulff, et al., the hydrolysis was carried out in water, which is a physiologically acceptable medium [page 93, lines 36-39]. As applied to claims 10 and 11, S is a monosaccharide containing at least one free hydroxyl function, R'' is methyl, and R_5 is benzyl.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Kametani, et al. (J. Am. Chem. Soc. 1987, 109, 3010-3017).

Claim 2 is drawn to the composition of claim 1, wherein, R_2 represents, generally, an alkyl, alkoxy, or alkyl amine.

Kametani, et al. teach compound 23 (shown below) [Table 1, Entry 1]. In this case, $m=0$, $R_1 = H$, and X and Y are OCH_3 . The compound is formed in acetone [Table 1, condition D]. Since acetone is used in nail polish remover, it is considered a "physiologically acceptable medium" that is compatible with the skin and the nails. This rejection also applies to claim 1, from which claim 2 depends.



No claims are allowed in this application. The elected species of compound G appears to be free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Bland whose telephone number is (571) 272-9572. The examiner can normally be reached on M-R 8:00AM-5:00PM UST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ldb


CECILIA TSANG
SUPERVISORY PATENT EXAMINER